2021年5月19日

## Maxim Group LLC による当社レポートの発表に関するお知らせ

現地時間の 2021 年 5 月 18 日、米国ニューヨーク州の投資銀行 Maxim Group LLC の Jason McCarthy 博士による、当社の 2021 年 12 月期 第 1 四半期の決算発表に基づくレポートが発表されましたので、参考情報としてお知らせいたします。

当該レポートは、恐れ入りますが、権利の都合上、英文のままでのご案内となりますので、 ご了承ください。

【Maxim Group LLC 公式 web サイト】

https://www.maximgrp.com/

MediciNova, Inc. (メディシノバ・インク)

東京事務所 IR 担当

E-mail <u>infojapan@medicinova.com</u>

URL https://medicinova.jp/





## **Biotechnology**

May 18, 2021
\$4.09 Buy \$15.00 \$3.87 - \$13.25 199.5 48.8 95.0% 949.6 \$0.0 \$0.00 0.0% Speculative
December

Total Expenses ('000)									
	2020A	2021E	2022E						
1Q	2,924	4,202A	8,484						
2Q	4,510	4,329	8,853						
3Q	3,730	4,463	9,591						
4Q	3,013	4,602	9,960						
FY	14,178	17,596	36,889						
Prior	_	22.259	40.980						



Jason McCarthy, Ph.D. (212) 895-3556 jmccarthy@maximgrp.com

Michael Okunewitch (212) 895-3579 mokunewitch@maximgrp.com

# MediciNova, Inc.

Buy

Quarter Update; Awaiting MN-166 Updates Across Pipeline, Strong Balance Sheet – Reiterate Buy

## Summary

- MediciNova reported 1Q21 results on 5/13/21 with revenues of \$4M resulting from two milestone payments. The company also reported a net loss of (\$0.2M) and ended the period with \$76.3M in cash on the balance sheet, which should provide sufficient runway through 2022 to fund the company's multiple latestage programs.
- The milestone payments were received under an agreement with Genzyme Corporation, a subsidiary of Sanofi (SNY - NR), as a result of the company achieving two clinical development milestones in March for a gene therapy product based on adeno-associated virus (AAV) vector technology.
- MN-166 programs: management continues to advance its multi-staged asset, MN-166, in various programs, including a P3 in amyotrophic lateral sclerosis (ALS); P3 in degenerative cervical myelopathy (DCM); P2b in chemotherapyinduced peripheral neuropathy; P1/2 in glioblastoma (GBM). Further updates from the trials are expected over the remainder of 2021.

## Details

MN-166. MN-166 (ibudilast) is a small molecule inhibitor of macrophage migration inhibitor factor (MIF) and phosphodiesterase-4 (PDE-4) as well as attenuation of activated glial cells. The drug has a de-risked safety profile due to it being marketed in Japan for post-stroke dizziness (another neurological disease) for two decades. Neuroinflammation has emerged as a therapeutic target across multiple neurodegenerative diseases. The lead indication is ALS, with a P3 ongoing. In P1b/2a, MN-166 demonstrated a 29.4% response rate on the ALSFRS-R functional rating scale compared to 17.6% for placebo. MN-166 has also demonstrated promising results in MS with P2b efficacy data that compared favorably to existing approved therapies (in cross-trial comparisons). The company is currently in the process of discussing potential partnerships for its P3 study in progressive MS. In addition, MN-166 is being developed for a number of other neurodegenerative diseases including degenerative cervical myelopathy (P3 ongoing), chemotherapy-induced peripheral neuropathy (P2b ongoing), and glioblastoma (P1/2 ongoing, funding to start potential registration enabling study secured).

Recall MN-166 is also being developed as a medical countermeasure against chlorine-gas induced lung injury, such as acute respiratory distress syndrome (ARDS) and acute lung injury (ALI). Notably, MN-166 is the first compound to receive development support through BARDA's Division of Research, Innovation, and Ventures' (DRIVe) Repurposing Drugs in Response to Chemical Threats (ReDIRECT) program, providing further validation to the compound's potential.

MN-001. MediciNova's second drug candidate, MN-001, is an antifibrotic drug that targets multiple mechanisms to address fibrosis, including reduction of gene expression involved fibrosis and inflammation, inhibition of leukotriene and phosphodiesterases, and reduction of triglycerides and is de-risked due to prior results in asthma (safety in >600 patients). MediciNova is currently targeting NASH and idiopathic pulmonary fibrosis (IPF). NASH is a complex disease, likely requiring multiple mechanisms. Considering MN-001 targets multiple mechanisms, we see a higher probability of success in NASH vs. similar stage therapeutics. The drug has demonstrated positive P2 data in triglyceride profiles in NASH/NAFLD patients (study terminated early for efficacy); next step would be a P2 in biopsy confirmed NASH. In IPF, MN-001 is being evaluated in a P2 study that recently completed patient enrollment.

## MediciNova, Inc. (MNOV)

MediciNova.: Income Statement (\$000)																	
YE December 31 Revenue:	2019A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Revenue:																	
MN-166 - ALS (WW)	-	-	-	-	-	-	-	-	33,247	92,262	154,810	232,188	302,626	362,165	428,241	482,120	525,940
MN-166 - Glioblastoma (WW)	-	-	-	-	-	-	-	-	-	-	34,482	83,223	160,465	218,176	280,278	319,302	361,017
MN-166 - Substance Dependence (US)								-	-	-	-	56,958	115,847	183,301	239,726	270,108	301,622
MN-001 Idiopathic Pulmonary Fibrosis (US)											_	15,529	47,804	81,754	117,445	137,729	158,992
MN-001 NASH (US)												12,710	65,212	107,065	137,327	169,097	216,892
												, .		. ,	- ,-	,	
Net revenue	-	-	-	-	-	-	-	-	33,247	92,262	189,292	400,608	691,955	952,461	1,203,018	1,378,356	1,564,463
Collaborative revenue: Revenues			4,000				4,000										
Other Income	_	_	4,000				4,000	_	_	-	_	_	_	_	_	_	_
	-	-					-	-	-	-	-	-	-	-	-	-	-
Total Collaborative Revenue	-	-	4,000	-	-	-	4,000	-	-	-	-	-	-	-	-	-	
Total Revenue		•	4,000	•	•	-	4,000	-	33,247	92,262	189,292	400,608	691,955	952,461	1,203,018	1,378,356	1,564,463
Gross Margins: Cost of Goods Sold			_	_	_	_	_		9,974	25,833	47,323	88,134	138,391	190,492	240,604	275,671	312,893
	ss Margin		-			-	-	-	70%	72%	75%	78%	80%	80%	80%	80%	80%
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	oo margiir								7070	1270	1070	1070	0070	5070	0070	0070	0070
Gross Profit	-	-	4,000	-	-	-	4,000	-	23,273	66,428	141,969	312,474	553,564	761,969	962,414	1,102,685	1,251,570
Operating Expenses:																	
Research and Development	6,07 %R&D	7,485	2,145	2,253	2,365	2,483	9,246	21,870	26,244	31,492	37,791	39,680	41,664	43,747	45,935	48,232	50,643
Selling, General and Administrative	7,95	6,693	2,056	2,077	2,098	2,119	8,349	15,019	20,319	24,383	29,260	35,112	38,623	42,486	46,734	51,407	56,548
3,	%SG&A	.,	,		,	, ,	-,-	.,.	-,	,	.,	,		,	-, -	. , .	,-
Total Expenses	14,03		4,202	4,329	4,463	4,602	17,596	36,889	56,537	81,709	114,374	162,926	218,678	276,725	333,272	375,310	420,084
Operating Income (Loss)	(14,03	(14,178)	(202)	(4,329)	(4,463)	(4,602)	(13,596)	(36,889)	(23,290)	10,553	74,918	237,682	473,276	675,736	869,745	1,003,046	1,144,379
Interest income	1,14	361	37				37	-	-	-	-	-	-	-	-	-	-
Other expense	(4		(23)				(23)	-	-	-	-	-	-			-	-
	-		( - /				- '	-	-	-	-	-	-	-	-	-	-
	-	-					-	-	-	-	-	-	-	-	-	-	-
Total Other Income	1,10	323	14				- 14	-	-	-	-	-	-	-	-	-	-
Pretax Income	(12,92		(188)	(4,329)	(4,463)	(4,602)	(13,582)	(36,889)	(23,290)	10,553	74,918	237,682	473,276	675,736	869,745	1,003,046	1,144,379
Income tax (expense)	(1			.,,,,,													
Towns on least		(0)												40.545	40.407	00.044	444.400
Taxes on income Tax Rate	-	(2)	-	-	-	-	-	-	-	-	-	-	-	13,515	43,487 5%	80,244	114,438 10%
GAAP Net Income (Loss)	(12,94	2) (13,854)	(188)	(4,329)	(4,463)	(4,602)	(13,582)	(36,889)	(23,290)	10,553	74,918	237,682	473,276	662,221	826,258	922,802	1,029,941
Foreign currency translation adjustments		4	7				7										
Total comprehensive loss	(12,94	2) (13,849)	(181)	(4,329)	(4,463)	(4,602)	(13,575)	(36,889)	(23,290)	10,553	74,918	237,682	473,276	662,221	826,258	922,802	1,029,941
			ì		```		· · ·	(,,									77-
GAAP-EPS	(0.3		(0.00)	(0.09)	(0.09)	(0.10)	(0.29)	(0.76)	(0.46)	0.21	1.46	4.61	9.13	12.73	15.82	17.60	19.56
GAAP-EPS (Dil) Wgtd Avg Shrs (Bas) - '000s	(0.3 43,15		(0.00) 47,535	(0.09) 47,583	(0.09) 47,630	(0.10) 47,678	(0.29) 47,607	(0.76) 48,547	(0.46) 50,996	0.21 51,201	1.46 51.406	4.61 51.612	9.13 51,818	12.73 52,026	15.82 52.234	17.60 52.444	19.56 52,654
Wgtd Avg Shrs (Bas) - '000s Wgtd Avg Shrs (Dil) - '000s	43,15 43.15		47,535 47,535	47,583 47,583	47,630 47,630	47,678 47,678	47,607 47,607	48,547 48,547	50,996 50,996	51,201 51,201	51,406 51,406	51,612 51,612	51,818 51,818	52,026 52,026	52,234 52,234	52,444 52,444	52,654 52,654
Source: Company reports and Maxim	45,15	, ,,,,13	77,000	77,000	47,000	47,070	71,001	70,047	50,550	31,201	51,700	01,012	31,010	02,020	JZ,2J4	JZ,744	52,054

Source: Company reports and Maxim

Maxim Group LLC 2

#### **DISCLOSURES**



Maxim	Group LLC Ratings Distribution	As of: 05/17/21	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	86%	54%
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	14%	52%
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	0%	0%
	*See valuation section for company specific relevant indices		

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

I, Michael Okunewitch, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

## Maxim Group makes a market in MediciNova, Inc.

Maxim Group expects to receive or intends to seek compensation for investment banking services from MediciNova, Inc. in the next 3 months.

MNOV: For MediciNova, we use the BTK (NYSE Arca Biotechnology Index) as the relevant index.

#### **Valuation Methods**

**MNOV:** We model commercialization of MN-166 for ALS in 2023, glioblastoma in 2025, and substance dependence in 2026 with a 70% risk adjustment, and of MN-001 in NASH and IPF in 2026 with an 80% and 70% risk adjustment, respectively. A 30% discount is applied to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target.

Maxim Group LLC 3

#### **Price Target and Investment Risks**

MNOV: Aside from general market and other economic risks, risks particular to our price target and rating for Medicinova include: (1) the regulatory and clinical risk associated with product development; (2) the ability to access capital and the very high likelihood that the company will need to raise additional capital; (3) the rate and degree of progress of product development; (4) the rate of regulatory approval and timelines to potential commercialization of products; (5) the reliance on collaborators and/or potential collaborators from which there could be unforeseen delays and expenses; (6) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (7) the liquidity and market volatility of the company's equity securities; (8) regulatory and manufacturing requirements and uncertainties; (9) product and technology developments by competitors; (10) inability, if product(s) is/are approved to gain adequate market share and maintain adequate revenue growth; (11) the ability of the company to maintain its exchange listing; (12) the ability of the company to enroll clinical trials, and may impact the commercial viability of MN-166 as a treatment for COVID-19 ARDS.

### **RISK RATINGS**

Risk ratings take into account both fundamental criteria and price volatility.

**Speculative** – <u>Fundamental Criteria:</u> This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. <u>Price Volatility:</u> Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

**High** – <u>Fundamental Criteria:</u> This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. <u>Price Volatility:</u> The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

**Medium** – <u>Fundamental Criteria:</u> This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

**Low** – <u>Fundamental Criteria:</u> This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

#### **DISCLAIMERS**

Some companies that Maxim Group LLC follows are emerging growth companies whose securities typically involve a higher degree of risk and more volatility than the securities of more established companies. The securities discussed in Maxim Group LLC research reports may not be suitable for some investors. Investors must make their own determination as to the appropriateness of an investment in any securities referred to herein, based on their specific investment objectives, financial status and risk tolerance.

This communication is neither an offer to sell nor a solicitation of an offer to buy any securities mentioned herein. This publication is confidential for the information of the addressee only and may not be reproduced in whole or in part, copies circulated, or disclosed to another party, without the prior written consent of Maxim Group, LLC ("Maxim").

Information and opinions presented in this report have been obtained or derived from sources believed by Maxim to be reliable, but Maxim makes no representation as to their accuracy or completeness. The aforementioned sentence does not apply to the disclosures required by FINRA Rule 2241. Maxim accepts no liability for loss arising from the use of the material presented in this report, except that this exclusion of liability does not apply to the extent that such liability arises under specific statutes or regulations applicable to Maxim. This report is not to be relied upon in substitution for the exercise of independent judgment. Maxim may have issued, and may in the future issue, other reports that are inconsistent with, and reach different conclusions from, the information presented in this report. Those reports reflect the different assumptions, views and analytical methods of the analysts who prepared them and Maxim is under no obligation to ensure that such other reports are brought to the attention of any recipient of this report.

Past performance should not be taken as an indication or guarantee of future performance, and no representation or warranty, express or implied, is made regarding future performance. Information, opinions and estimates contained in this report reflect a judgment at its original date of publication by Maxim and are subject to change without notice. The price, value of and income from any of the securities mentioned in this report can fall as well as rise. The value of securities is subject to exchange rate fluctuation that may have a positive or adverse effect on the price or income of such securities. Investors in securities such as ADRs, the values of which are influenced by currency volatility, effectively assume this risk. Securities recommended, offered or sold by Maxim: (1) are not insured by the Federal Deposit Insurance Company; (2) are not deposits or other obligations of any insured depository institution; and (3) are subject to investment risks, including the possible loss of principal invested. Indeed, in the case of some investments, the potential losses may exceed the amount of initial investment and, in such circumstances, you may be required to pay more money to support these losses.

### ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

Maxim Group LLC 4



# **Corporate Headquarters**

The Chrysler Building 405 Lexington Ave., 2nd FL New York, NY 10174

Tel: 212-895-3500

Capital Markets/Syndicate: 212-895-3695

Corporate Finance: 212-895-3811
Corporate Services: 212-895-3631
Equity/Options Trading: 212-895-3790

Equity Research: 212-895-3736

Fixed Income Trading: 212-895-3875

Woodbury, Long Island

100 Crossways Park Drive West Suite 207

Woodbury, NY 11797 Tel: 516-393-8300

West Palm Beach, Florida

105 South Narcissus Avenue Suite 222

West Palm Beach, FL 33401

Tel: 561-508-4433

Aventura, Florida

20801 Biscayne Blvd Suite 432 / 433 Aventura, FL 33180

Tel: 516-396-3120

Miami Beach 1000 5th Street, Suite 229 Miami Beach, FL 33139

Tel: 786-864-0880

Global Equity Trading: 212-895-3623

Institutional Sales: 212-895-3873

Institutional Sales Trading: 212-895-3873
Portfolio/Transition Trading: 212-895-3567

Prime Brokerage: 212-895-3723

Wealth Management: 212-895-3624

Red Bank, New Jersey

246 Maple Avenue Red Bank, NJ 07701 Tel: 732-784-1900

San Rafael, California

4040 Civic Center Drive Suite 200 San Rafael, CA 94903

Tel: 212-895-3670

Stamford, Connecticut

700 Canal Street Stamford, CT 06902